

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: Ethicon Wave 3 cases listed in Exhibit A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION
TO LIMIT THE GENERAL OPINIONS OF
DEFENSE EXPERT WENXIN ZHENG, M.D.**

Defense expert Wenxin Zheng, M.D., is a pathologist. Previously in this litigation, and/or in the New Jersey litigation, Dr. Zheng has admitted that he has no expertise in any of the following areas: surgery, comparing heavyweight and lightweight mesh, the materials from which Ethicon's mesh is made, engineering, medical devices generally, degradation, whether Ethicon's mesh is inert, the clinical impact of Ethicon's mesh, pain generally, cytotoxicity, and whether Ethicon's mesh products are the "gold standard."

In the federal and state mesh litigations, Dr. Zheng has been proffered several times as a pathology expert in specific cases. But now in Ethicon Wave 3, Dr. Zheng has suddenly been proffered as a general expert who has numerous opinions about those subject areas on which he previously admitted a lack of expertise. The Court should reject all of the new opinions that Dr. Zheng is unqualified to give, and should thereby limit his opinions to those regarding pathology.

Dr. Zheng lists two types of opinions in his report. First, he asserts that the TVT and TVT-O devices are the "standard of care"—an opinion that he previously agreed he was not

qualified to give—and lists seven reasons for this conclusion. All seven reasons derive from topics on which Dr. Zheng has no qualifications to offer opinions: the properties of the mesh, the clinical impacts of the mesh, and cancer. Next, Dr. Zheng criticizes several aspects of the report submitted by Dr. Vladimir Iakovlev, a pathology expert for the Plaintiffs. First, Dr. Zheng criticizes Dr. Iakovlev for his supposed failure to recognize that the TVT and TVT-O are the “gold standard”—an opinion that Ethicon previously did not challenge as falling outside of Dr. Zheng’s expertise. Dr. Zheng then lists seven specific criticisms, three of which are based on pathology and are, therefore, not being challenged by this motion. Opinions 2 and 3 require clinical expertise, which Dr. Zheng does not have; Opinion 6 requires expertise in materials and is also unsupported; and Opinion 7 relates to degradation, an area in which Dr. Zheng has expressly disclaimed expertise. Thus, opinions 2, 3, 6 and 7 criticizing Dr. Iakovlev should be also excluded.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents “scientific knowledge,” meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert’s opinions “fit” the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

Courts should focus on expert witnesses’ “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

ARGUMENT

Dr. Zheng’s opinions that go beyond the realm of pathology should be excluded for lack of qualifications. In addition, his opinion criticizing Dr. Iakovlev for relying in part on meshes used to treat pelvic organ prolapse should be excluded for lack of analysis or support. This brief will first address the prior admissions regarding Dr. Zheng’s lack of expertise, and then will explain how those admissions relate to the testimony that he now seeks to offer.

I. Dr. Zheng has given numerous prior admissions about his lack of expertise; most notably, he has disclaimed any expertise regarding the properties of the mesh and regarding the clinical impacts of the mesh.

Dr. Zheng was designated as an expert witness in one Ethicon case that went to trial, the *Huskey* case. In his deposition for *Huskey*, Dr. Zheng made several admissions regarding his lack of expertise outside the realm of pathology:

- “I don’t think I’m an expert for overall, like the mesh and related issues, but I have been considered an expert in the GYN pathology, gynecological pathology.”¹

¹ Zheng *Huskey* Deposition, April 3, 2014, attached as Exhibit B, at 11:20-12:1.

- “Correct. I am not a material expert.”²
- “I’m not [an] engineer expert.”³
- “I’m not a medical device expert”⁴
- “I’m not a surgeon.”⁵
- “As I said, I’m not the material expert. But overall I think, based on my evaluation, pathological evaluation from these meshes, I’m not able to tell this mesh is lightweight versus heavyweight.”⁶
- (Q. In your opinion, is polypropylene chemically inert?) “I’m not sure, because I’m not – I did not study this, and also I’m not [an] expert for the material.”⁷
- “[W]hat’s the criteria to make TVT or TVT-O as the standard of care I think I’m not going to – I’m not [an] expert for the clinical aspects.”⁸
- (Q. Are you a pain expert?) “No.”⁹
- (Q. And are surface cracks an indication of degradation?) ... “I don’t want to go too far, because I already stated I’m not [an] expert – material expert, so this is beyond my expertise. I’m a pathologist.”¹⁰
- (Q. But anything related to materials and polypropylene degradation, you don’t feel like you’re qualified to testify about that?) “Correct.”¹¹

Based in part on those admissions, the *Huskey* Plaintiffs moved to exclude 11 opinions as outside of Dr. Zheng’s expertise. Ethicon did not contest eight of those arguments, as reflected in this Court’s Order:

Ethicon conceded that Dr. Zheng will not opine on several of these topics. Accordingly, the plaintiffs’ motion is **DENIED as moot** with respect to the

² *Id.* at 62:23-25.

³ *Id.* at 63:1-2.

⁴ *Id.* at 63:3-8.

⁵ *Id.* at 83:16-21.

⁶ *Id.* at 84:3-9.

⁷ *Id.* at 90:3-6.

⁸ *Id.* at 106:7-14.

⁹ *Id.* at 203:14-15.

¹⁰ *Id.* at 215:6-216:3.

¹¹ *Id.* at 217:6-9.

following opinions: (1) whether heavy or light-weight mesh is preferable, (2) whether complications for mesh devices were underreported by manufacturers including Ethicon, (3) the causes of mesh erosion and whether the TVT–O causes erosion, (4) electron microscopy, (5) opinions requiring expertise of a materials expert, an expert on medical devices, or a biomedical engineer, (6) opinions related specifically to Ms. Huskey’s pathology, (7) the surgical standard of care for Ms. Huskey’s procedures and precise details of surgical techniques, and (8) that the TVT–O is the gold standard for treatment of SUI.

Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 732 (S.D. W. Va. 2014) (footnotes omitted). The Court ruled for Ethicon on two of the three contested issues, but the Court held that “Dr. Zheng is not qualified to opine whether transvaginal mesh devices cause pain, and such opinions are **EXCLUDED.**” *Id.* at 733.

While the *Huskey* case was two years ago, there is nothing in Dr. Zheng’s materials for this case indicating that he has somehow gained new expertise. Notably, the CV that Ethicon included with his expert report is dated July 4, 2014.¹² Use of that CV indicates that Ethicon does not believe any of his experience after that date is essential to his opinions.

In addition, Dr. Zheng was deposed in late 2015 for the New Jersey litigation, and he made many similar admissions regarding his lack of expertise—thereby indicating that the admissions and resulting decisions in *Huskey* remain valid:

- (Q. Is it fair to say you would defer to physicians who have performed a pelvic examination concerning their differential diagnosis of Mrs. Corbet?) “That’s not my – my expert field. I provided [a] pathological finding, you know, opinion regarding what I have observed under the microscope.”¹³
- (Q. What degree or grade of a rectocele can cause inflammation?) “And, again, I – I’m not a surgeon, number one. And I do not perform these surgeries. And what I – my expertise is within the pathology field. So I think these questions are best answered by the surgeon.”¹⁴

¹² Zheng CV, attached as Exhibit C.

¹³ Zheng Dep. in *Corbet v. Ethicon, Inc.*, BER-L-11575-14 (N.J. Sup. Ct.), Nov. 18, 2015, attached as Exhibit D, at 116:5-12.

¹⁴ *Id.* at 130:25-131:7.

- “Yeah, this one, lightweight, heavyweight, these mainly belong to material experts.”¹⁵
- (Q. And you’re not offering opinions on clinical findings?) “Correct. Because I’m not – I don’t have expertise like that.”¹⁶
- (Q. ... [D]o you have an opinion whether or not cytotoxicity can cause erosion?) ... A. “I’m not going to offer any opinion of that.” (Q. Would you defer to people at Ethicon?) A. Or the expert.”¹⁷

These admissions, plus Ethicon’s previous failure to even advocate for Dr. Zheng’s expertise on several issues, plus this Court’s prior order preventing him from opining about whether Ethicon’s mesh causes pain, demonstrate that Dr. Zheng’s expertise is limited to the world of pathology. As someone who is not a materials expert and has no expertise in degradation, Dr. Zheng is not qualified to opine about the properties of the mesh. As someone who is not an expert in clinical issues and is not an expert in pain, he is not qualified to opine about the effects of the mesh on women. And, as someone who is not a surgeon, Dr. Zheng does not have the clinical experience to opine about issues such as whether Ethicon’s meshes are the “standard of care” or the “gold standard.”

II. The large majority of Dr. Zheng’s opinions should be excluded because they fall into categories where he, by his own admission, has no expertise.

Most of the opinions in Dr. Zheng’s general expert report go way beyond the realm of pathology, and all such opinions should be excluded due to his lack of expertise, as discussed above. This section of the brief will go through all of Dr. Zheng’s opinions to help the Court determine which opinions should be excluded and which are within the realm of his expertise.¹⁸

¹⁵ *Id.* at 163:17-23.

¹⁶ *Id.* at 167:15-18.

¹⁷ *Id.* at 274:13-21.

¹⁸ Of course, Plaintiffs’ decision not to challenge certain opinions under *Daubert* should not be taken as agreement with the content of the stated opinions.

- A. All of Dr. Zheng's "standard of care" opinions should be excluded because they require expertise in the properties of the mesh and its clinical effects, and Dr. Zheng has neither.

The Court should exclude entirely Dr. Zheng's first set of opinions, which are offered to support his conclusion that "Ethicon's TVT and TVT-O are the standard of care for the treatment of stress urinary incontinence in women."¹⁹ Notably, Dr. Zheng previously disclaimed his own expertise to give such a standard-of-care opinion, stating that he is "not [an] expert for the clinical aspects."²⁰ In addition, none of the seven opinions that allegedly support Dr. Zheng's standard-of-care opinion fall within Dr. Zheng's expertise.

Several of Dr. Zheng's opinions should be excluded because they address the properties of the mesh and how the mesh behaves after implantation; therefore, the opinions require expertise in materials that Dr. Zheng does not possess. The opinions that fall into this category are: (i) the TVT meshes produce a limited foreign body response²¹; (ii) the TVT meshes create "appropriate tissue integration"²²; (iv) fibrosis and scar plate formation occurs "normally" in the majority of implanted TVT and TVT-O meshes²³; (v) the mesh does not contract in vivo²⁴; and (vii) there is no evidence that the mesh is carcinogenic.²⁵ See *Huskey*, 29 F. Supp. 3d at 732 (noting Ethicon's failure to challenge the argument that Dr. Zheng was unqualified to offer "opinions requiring expertise of a materials expert, an expert on medical devices, or a biomedical engineer").²⁶ As to opinion (vii), it should also be excluded because there is nothing in Dr.

¹⁹ Expert Report of Wenxin Zheng, M.D., June 3, 2016, attached as Exhibit E, at p. 6.

²⁰ Zheng *Huskey* Dep., Ex. B, at 106:7-14.

²¹ Zheng Report, Ex. E, at 6-7.

²² *Id.* at 7.

²³ *Id.* at 8.

²⁴ *Id.* at 8-9.

²⁵ *Id.* at 10.

²⁶ As noted above, Dr. Zheng also several times disclaimed any expertise in the properties of the mesh during his *Huskey* deposition.

Zheng's profile indicating that he has the expertise to opine as to whether the TVT meshes can cause cancer, and because his very short opinion is almost entirely unsupported.²⁷

The remaining two opinions as to the standard of care should be excluded because of Dr. Zheng's admitted lack of expertise in the clinical effects of meshes. *See Huskey*, 29 F. Supp. 3d at 733. These opinions are that (iii) the TVT does not "potentiate infection due to its material properties,"²⁸ and that (vi) there is little or no correlation between implantation of the TVT and pain.²⁹ As noted above, in *Corbet* Dr. Zheng testified that diagnosing the patient was outside of his expertise, stating that he "provided [a] pathological finding, you know, opinion regarding what I have observed under the microscope."³⁰ He further stated that he was giving no clinical opinions because "I don't have expertise like that."³¹ In *Huskey*, he disclaimed any expertise in "the clinical aspects" of mesh,³² and he testified that he is not an expert in pain.³³

Because none of Dr. Zheng's opinions that support his standard of care opinion fall within the scope of his expertise, his standard-of-care opinion should be excluded entirely—along with all seven secondary opinions that support that opinion.

B. Many of Dr. Zheng's opinions that criticize Dr. Iakovlev's findings are beyond Dr. Zheng's expertise and/or wholly unsupported by analysis or evidence.

The Court should also exclude several of the opinions that attack Dr. Iakovlev, a pathology expert retained by the Plaintiffs. The opinions Plaintiffs are **not** challenging are Nos. (1), (4) and (5). These opinions criticize Dr. Iakovlev's work as a pathologist, and while

²⁷ Dr. Zheng does not explain why rat studies cannot be "extrapolated to the human experience," and while he cites three articles as alleged support for his opinion, he does not give any details about the articles or make any effort to explain away contrary evidence.

²⁸ Zheng Report, Ex. E, at 8.

²⁹ *Id.* at 9-10.

³⁰ Zheng *Corbet* Dep., Ex. D, at 116:5-12.

³¹ *Id.* at 167:15-18.

³² Zheng *Huskey* Dep., Ex. B, at 106:7-14.

³³ *Id.* at 203:14-15.

Plaintiffs do not agree with the criticism, they do not claim that such opinions are outside of Dr. Zheng's expertise.

However, the remaining opinions should be excluded.³⁴ Opinions No. 2 and 3 again fall into the realm of clinical evaluations. Opinion No. 2 asserts that Dr. Iakovlev's findings do not "correlate with dyspareunia or pelvic/vaginal pain."³⁵ Similarly, No. 3 criticizes Dr. Iakovlev's assertions regarding nerve pain.³⁶ Again, the Court has already rejected Dr. Zheng's expertise in this area, *Huskey*, 29 F. Supp. 3d at 733, and Dr. Zheng has admitted his lack of expertise regarding the clinical effects of mesh, including pain.³⁷

Opinion No. 6 should be excluded both as falling under materials expertise and as wholly unsupported. Dr. Zheng criticizes Dr. Iakovlev for relying, in part, on meshes used to treat pelvic organ prolapse ("POP"), rather than stress urinary incontinence ("SUI").³⁸ Clearly, understanding the relevance—if any—of this distinction would require expertise in materials, and, as already discussed, Dr. Zheng has no such expertise. Dr. Zheng also completely fails to explain why findings from meshes used to treat POP could not be used to support findings as to meshes used to treat SUI. Thus, opinion No. 6 is both outside of Dr. Zheng's qualifications and entirely unreliable. Finally, opinion No. 7 attacks Dr. Iakovlev's assertion that the TVT mesh degrades.³⁹ Again, Dr. Zheng has disclaimed expertise in degradation,⁴⁰ and this Court has noted that his lack of expertise in materials issues was uncontested. *Huskey*, 29 F. Supp. 3d at

³⁴ In addition to his numbered opinions, Dr. Zheng criticizes Dr. Iakovlev for his failure to recognize that Ethicon's meshes are supposedly the "gold standard." (Zheng Report, Ex. D, at 10). In *Huskey*, the Plaintiffs moved to exclude that opinion as outside of Dr. Zheng's expertise, and Ethicon capitulated. *Huskey*, 29 F. Supp. 3d at 732.

³⁵ Zheng Report, Ex. E, at 11.

³⁶ *Id.*

³⁷ Zheng *Corbett* Dep., Ex. D, at 167:15-18; Zheng *Huskey* Dep., Ex. B, at 203:14-15.

³⁸ Zheng Report, Ex. E, at 12.

³⁹ *Id.*

⁴⁰ Zheng *Huskey* Dep., Ex. B, at 217:6-9.

732. Thus, Dr. Zheng is unqualified to assess whether Dr. Iakovlev offers “scientifically reliable evidence” regarding degradation, and his opinion should be excluded.

CONCLUSION

For all of the foregoing reasons, this Court should exclude many of Dr. Zheng’s opinions. Plaintiffs respectfully request that the Court exclude his standard-of-care opinion, including all of the secondary opinions that support his standard-of-care opinion, and that the Court exclude opinions No. 2, 3, 6 and 7 in the section criticizing Plaintiffs’ expert Vladimir Iakovlev. All of these opinions fall outside of Dr. Zheng’s expertise, as evidenced by Dr. Zheng’s own testimony and Ethicon’s prior failure to contest similar arguments. In addition, certain opinions are unsupported and, therefore, unreliable, as described above.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on September 19, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Thomas P. Cartmell

Attorney for Plaintiffs